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Cosmetics That 'Do Something' A Regulatory Compliance Challenge

By Ryan Nelson

Competitive players in today's cosmetics market are under pressure to claim that their products 'do something' in a structure/function sense, but that something is often what triggers an FDA warning letter, food and drug attorney Katherine Giannamore observed in a March 30 interview.

Giannamore, who heads her own law firm in Coral Gables, Fla., routinely works with cosmetics firms to assess risk associated with product claims and appreciates the challenges companies face in promoting their offerings effectively without inviting FDA enforcement action.

"Usually they want to push the envelope – a lot of times way too far. So what I do is scale them back, pointing out what things are definitely going to get you in trouble while keeping in mind that the product has to do something," she said.

"What can be a problem is willingness to change something like 'Gets rid of wrinkles' to 'Minimizes the appearance of wrinkles,' because it can be wordy or less attractive. That's where we run into issues," she noted.

Typically, the process is an exercise in "how much risk people want to take on," according to the attorney.

She explained: "There's really no way around it. There's no way of saying your product does something while still being totally cosmetic. So it's a matter of finding creative ways" to convey product benefits without violating the Federal Food, Drug and Cosmetic Act's definition of a cosmetic, which limits the field to products that cleanse, beautify or alter users' appearance.

Drugs, on the other hand, can be promoted as affecting the body's structure or function.

Giannamore suggested that investing in regulatory counsel prior to market can be advantageous for small companies, particularly when comparing the associated expense with the potential costs of resolving an FDA warning letter.

"A lot of people come to me and they already have an FDA warning letter, or they're importing and they've been stopped," due to excessive claims or other issues that "really shouldn't be there," the lawyer said. Often "it's due to lack of resources in the beginning or it just not being something that's high on the totem pole because they're thinking, 'We're a small company, they're not going to target us.'"

But small and large companies alike have drawn warning letters in recent months, from Irvine, Calif.-based biotech firm **Invitrx Therapeutics Inc.**, which markets *Reluma* anti-aging cosmetics based on its adult stem-cell technology platform, to **L'Oreal S.A.**, cited in February for claims promoting *La Roche-Posay* skin-care products ("'Revolution' Quelled? FDA Warns Firm For ReLuma Stem-Cell Claims" – "The Rose Sheet," Dec. 3, 2014 *and* "FDA Warning To L'Oreal Creates Uncertainty For Anti-Redness, Dark Spot Treatments" – "The Rose Sheet," Feb. 25, 2015).

The cost of addressing a warning letter and implementing corrective measures can be substantial, particularly for companies with more limited resources. EAS Consulting Group's John Bailey, former director of FDA's cosmetics program and chief scientist at the Personal Care Products Council, pointed out in a recent interview that FDA may require relabeling in cases where claims render cosmetics unapproved drugs, and the agency can direct companies to halt product shipments in the interim ("Regulatory Roulette: Playing In Today's Skin-Care Market A Gamble" – "The Rose Sheet," Mar. 17, 2015).

Regardless of a company's size, an FDA warning is a problem from a PR standpoint, Giannamore noted.

"If anybody's ever Googling you, that's now the first thing that comes up. And it's not like people are going to go on and read the warning letter and say, 'This isn't such a big deal because FDA only targeted them for a claim.' They're just going to say, 'Oh my God, they have a warning letter; don't buy their product."

Additionally, warning letters place companies squarely in FDA's sights, and companies may be monitored more closely by the agency going forward. L'Oreal's recent warning letter was the firm's second in three years, suggesting that offenders may remain on FDA's radar.

"It's the sense that now they know who you are, where you are, and that you've [erred] in the past, so there is this possibility that you might do it again," Giannamore said.

Moving on from a warning letter also can be difficult because the back-and-forth with FDA often leaves companies wanting a more decisive resolution to the process, the attorney suggested.

"They [FDA] are very unwilling to formally say, 'Here's a closeout letter and you're done.' What normally happens is they take a firm's response, they say, 'Thank you. We'll let you know if there's anything else.' Usually, there's nothing further … but there's also no official ending."

Companies do have the option of challenging FDA's position in their response to a warning letter. The agency asks recipients for an explanation of steps they are taking to correct violations or their reasoning, along with supporting information, for why cited products are not in violation of the law.

However, in Giannamore's experience, companies have not been inclined to take the latter course.

"I tell people, 'If that's what you want to do…' But it's not going to end with the next person [at FDA] saying, 'You know what? I think you're right.' It's just going to drag on and on. If you want to spend years and thousands of dollars, that's one thing, but the other thing you could do is, even if you disagree, just try to comply so you can get back to what's important to you – staying in business and selling products."